

**Amendments to the Specification**

Please replace the paragraph beginning at page 1, line 2 with the following rewritten paragraph:

This application claims the benefit of U. S. Provisional Application No. ~~60/466,223~~ 60/466,225, filed 04/28/2003 and is a continuation-in-part of United States Application Serial No. 10/246,347, filed 09/18/2002 which is a continuation of United States Patent Application Serial No. 10/201,363 filed 07/23/2002, claiming the benefit of United States Provisional Application No. 60/349,593 filed 01/18/2002.

Please replace the paragraph beginning at page 6, line 6 with the following rewritten paragraph:

(10) ~~Aekin~~ Arkin, H. *et al.*, "Recent Development In Modeling Heat Transfer in Blood Perfused Tissue." *IEEE Transactions on Bio-Medical Engineering*, 41 (2): 97-107 (1994).

Please replace the paragraph beginning at page 8, line 10 with the following rewritten paragraph:

Beneficial thermal compromization of target tissue volumes is not entirely associated with HSP based treatments for neoplastic tissue and other applications, for instance, having been studied in connection with certain aspects of angioplasty. Catheter-based angioplasty was first intentionally employed in 1964 for providing a transluminal dilation of a stenosis of an adductor hiatus with vascular disease. Balloon angioplasty of peripheral arteries followed with cautious approaches to its implementation to the dilation of ~~stenotic~~ stenotic segments of coronary arteries. By 1977 the first successful percutaneous transluminal coronary angioplasty (PTCA) was carried out. While, at the time, representing a highly promising approach to the treatment of angina pectoris, subsequent experience uncovered post-procedural complications. While PTCA had been observed to be effective in 90% or more of the subject procedures, acute reclosure, was observed to occur in approximately 5% of the patients. Stenosis was observed to occur in some patients within a period of a few weeks of the dilational procedure and restenosis was observed to occur in 15% to 43% of cases within six months of angioplasty. See generally:

Please replace the paragraph beginning at page 12, line 10 with the following rewritten paragraph:

In commonly owned co-pending application for United States patent serial No. 10/246,347, filed 09/18/2002 and entitled "System, Method and Apparatus for Localized Heating of Tissue", an approach to accurately carrying out an in situ elevation of the temperature of a target tissue volume is presented. Accuracy is achieved using ~~unteathered~~ untethered temperature sensor implants formed of ferromagnetic material which experiences an abrupt magnetic permeability state change within a very narrow temperature range. Temperature sensing is carried out by monitoring a very low level magnetic field extending through the position of the implant. For instance, the earth's magnetic field may be employed. Where inductively based heating is utilized, non-magnetic heaters may be implanted with the sensors and sensing is carried out intermittently in the absence of the inductably derived magnetic field.

Please replace the paragraph beginning at page 13, line 29 with the following rewritten paragraph:

The present invention is addressed to method, system and apparatus for accurately evaluating a temperature related physical parameter within the body of a patient. Accurate temperature measurement is achieved through the use of one or more teatherless temperature sensors strategically located within the body and configured with a passive resonant circuit. These passive circuits respond to an extra body applied excitation electromagnetic field by resonating at an identifiable unique resonant center frequency. In one embodiment, the resonant circuit based sensors are configured with a capacitor and a series coupled inductor formed with a winding disposed about a ferrite core. That ferrite core is formulated to exhibit a somewhat sharp permeability state change or transition at a Curie temperature corresponding with a desired temperature setpoint. With the arrangement, upon being excited by an applied excitation burst, the sensor will ring or resonate at its unique, signature resonant center frequency when at monitor temperatures below the involved Curie temperature. As the sensor witnesses monitoring temperatures approaching the Curie temperature defined setpoint the intensity of its unique resonant center frequency decreases, an aspect which may be taken advantage of from a temperature control standpoint. However, when the Curie or target temperature is reached, the relative permeability of the sensor's ferrite core drops sharply toward a unity value to, in turn, cause a sharp drop in the reluctance of the

~~associated inductor coil causing the resonant frequency of the device to shift~~ substantially upward in value. This shift is to an off-scale value. In effect, the signature output disappears. As the sensors resonate in response to excitation, the detector components of the associated interrogation system are capable of sensing all of the resonating devices, whereupon the sensed signals are digitized, averaged and analyzed to identify each sensor by its unique resonant center frequency, if at the noted monitor temperatures. Such analysis may be carried out using a Fourier transform-type approach. Because the unique resonant center frequency remains stable as the temperatures witnessed by the sensors, approach or transition toward the Curie temperature-based setpoint, the amplitude of the Fourier transform signal will diminish and the system has the capability of predicting the arrival of the Curie based setpoint temperature. Thermal overshoot can thus be more accurately accommodated for.

Please replace the paragraph beginning at page 14, line 29 with the following rewritten paragraph:

The instant method has ~~brought~~ broad application to thermotherapy endeavors including an in vivo induction of heat shock proteins, a procedure having important utility in the treatment of cancer, infectious diseases and other therapies. As another modality, one or more of the sensors is combined with an intra-luminal stent and when so combined and implanted, permit a non-invasive repeatable and accurate hyperthermia therapy for stenosis/restenosis.

Please replace the paragraph beginning at page 26, line 1 with the following rewritten paragraph:

The present invention employs temperature sensing ~~unteathered~~ untethered implants which are located within a target tissue volume, whereupon, using any of the above-discussed extra body heating systems the ~~unteathered~~ untethered implants will provide a quite accurate readout of preselected temperature levels. These temperature sensing implants are configured as passive resonant circuits with an inductor component and a capacitor component configured as a resonant circuit. That circuit is caused to ring at a known unique resonant center frequency while the tissue being monitored is at monitor temperatures below a target Curie temperature. When the predetermined setpoint (Curie-based) temperature for the tissue is reached, then the known resonating center frequency abruptly terminates. This sharp termination of resonance in conjunction with the known center frequency is achieved

by utilizing an inductor component comprised of a winding and a ferromagnetic core. The ferromagnetic core is formulated to evoke a Curie transition, for example, in magnetic permeability over relatively narrow temperature ranges, for instance, between about 0.1°C to about 5°C for use with sensors and as narrow as about 0.1°C to about 1°C for use with auto-regulating heaters. This transition in terms of relative magnetic permeability  $\mu_r$ , will be from about 100 to 1 to about 5000 to 1.

Please replace the paragraph beginning at page 31, line 8 with the following rewritten paragraph:

With this arrangement, a plurality of temperature sensing implants may be developed, each with a unique resonant center frequency. The particular resonant frequency which is utilized in carrying out temperature sensing of a target tissue volume in general, will fall within a range of from about 100 kHz to about 2 MHz. As is apparent from the above two expressions, when the circuit 90 is exposed to temperatures approaching the Curie temperature, relative permeability will drop to a value approaching one and, in consequence, the reluctance of the inductor east decreases and the associated signal output level issuing from the sensor decreases by 3-fold to 10-fold or more, indicating that the Curie temperature is close at hand. The above expressions also reveal that the various resonant frequencies employed with the system can be adjusted by controlling the number of turns 94 and the value of capacitance for capacitors as at 100. Accordingly, each temperature sensor implant will exhibit its own unique resonant center frequency based signature.

Please replace the paragraph beginning at page 33, line 18 with the following rewritten paragraph:

Also powered from low voltage linear power supply 156 as represented at arrows 162 and 164 is a front-end amplification function represented at 166 and an output amplification function represented at 168. The detected signals from sense antenna 118 are both amplified and filtered following a delay interval occurring subsequent to the excitation interval. That delay interval permits a sufficient dampening of the excitation ~~pause~~ pulse so as not to interfere with the resonating signals emanating from the sensor implant or implants. Note that cable 148 extends to the input of a front-end amplification stage 166. The output of the detector assembly also is seen to be amplified as represented at symbol 168. As part of the signal treatment, as represented at arrows 170 and 172, the sense antenna output is subjected to bandpass filtering as represented at block 174 as well as is stripped of

any d.c. term. The bandpass evoked by the filtering function 174 will extend from, for example, about 100 kHz to about 2 MHz.

Please replace the paragraph beginning at page 33, line 31 with the following rewritten paragraph:

The amplified sense output is directed, as represented at arrow 176 to a data acquisition and control network represented in general at block 178. This analog signal is sampled at a very high rate with an analog to digital conversion approach. With this digital approach, the system may apply the full power of signal averaging to lower baseline noise with respect to the associated function of identifying thermal sensor broadcast centerline frequency data. For example, utilizing a point-by-point approach averaging is carried out and resonant frequency data is derived. For that purpose, Fourier transform approaches are available including the fast Fourier transform (FFT). These functions are represented at block 178 as a data acquisition block 180, the digital output of which is represented at arrow 182. Arrow 182 extends to a data processing algorithmic function represented at block 184. This algorithm is responsive to the center frequency intensity signal and data representing a corresponding unique resonant electromagnetic response of an implant temperature sensor to derive implant status data as detector outputs. These Fourier-type outputs representing a unique resonant center frequency will diminish in amplitude as core Curie temperature is approached. A ratio of such ~~dimunition~~ diminution (instantaneous to maximum amplitude) is used for control and monitoring purposes. As represented at bus arrow 186 and block 188 resultant implant status data is asserted to a graphical user interface or readout assembly to provide visibly discernable information to the operator. Signals to instruct the system to commence carrying out an excitation and sensing sequence may be evolved from the data acquisition function 180. Such signal introduction is represented at arrow 190.

Please replace the paragraph beginning at page 51, line 12 with the following rewritten paragraph:

Referring to Fig. 19, a somewhat basic implementation of the system and method at hand is schematically represented. In the figure a patient is represented at 802 in a supine position on a support 804. Support 804 is formed of a material such as a polymer permitting excitation energy to be broadcast therethrough. A target tissue volume within the body of patient 802 is schematically represented at 806 having a distribution of implants as described in connection with Fig. 18. For instance, six of the implants may be lower threshold temperature sensors which will

resonate at temperatures approaching a Curie temperature of, for example, 40°C. The second grouping of six sensors will be structured to resonate at monitor temperatures approaching an upper limit value, for example, a Curie temperature 44°C. Located below the support 804 and at a location effective to cause the development of resonant outputs from the sensor implants is an excitation antenna 808 which is depicted as having a cable connection 810 with an excitation electronics assembly represented at block 812. Excitation electronics assembly 812 is configured for interactive communication with a receiver electronics assembly shown at block 814 as represented at dual dashed arrows 816. Arrows 816 may, for instance, be representative of opto-isolated communication lines. Control to excitation electronics assembly 812 and receiver electronics assembly 814 is represented by arrow 818 and a controller as represented at block 820. A sense antenna is represented schematically at 822. Antenna 822 may be flexible and essentially conform over or drape over the patient 802 in surrounding relationship about target tissue volume 806. The data acquisition and analysis components of controller 820 communicate as represented at arrow 824 with a readout schematically represented at 826. Readout or user interface 826 includes an on/off switch 828 and a measurement frequency input switch 831. The upper readout of device 826 at 830 includes an indicator apprising the operator of the lower threshold temperature elected for the therapy as represented at 832. In this regard, the indicator 832 shows a temperature of 40°C as being the Curie temperature of the inductor component ferrite core of six implants. Below the indicator 832 are two linear arrays of ~~visibly~~ visibly perceptible readouts implemented, for example, as light emitting diodes (LEDs). The upper array of LEDs is represented at 834 and is configured with six blue output LEDs each associated with a number which will be illuminated in the presence of monitoring temperatures below and approaching 40°C, i.e., below  $T_{min}$ . As shown by the numeric sequence of identifiers immediately above the LEDs of array 834, each LED is assigned to be illuminated in the presence of the select resonant center frequency of a given unique implant now numbered 1-6. Below LED array 834 is an LED array 838 comprised of six spaced apart green LEDs corresponding with the numeric array 836 and configured to be illuminated when their corresponding implant will have reached the elected relative amplitude of the processed counter frequency data at a temperature approaching the lower threshold Curie temperature of, for example, 40°C. Accordingly, the green LEDs of array 838 are illuminated when their corresponding sensor implants are above the lower

threshold temperature value of 40°C and are not illuminated at monitor temperatures below that value.

Please replace the paragraph beginning at page 52, line 22 with the following corrected paragraph:

A lower readout 840 is configured in the same manner as readout 830. Lower readout 840 includes a Curie temperature indicator 842 representing the programmed upper limit Curie temperature for the remaining six implants, for instance, 43°C. Each of the upper limit implants will have a unique resonant frequency when interrogated at monitor temperatures below 43°C and those unique resonant center frequencies will provide relative amplitude data of ~~dimishing~~ diminishing value at temperatures approaching that upper limit value. Lower readout 840 incorporates six yellow LED implemented visual readout components represented at linear LED array 844. LEDs within the array 844 will illuminate in a yellow coloration at monitor temperatures below and approaching the upper limit of 43°C, i.e., below T<sub>max</sub>. Each LED will be illuminated when its associated implant is resonating at its designated unique center frequency in the presence of monitoring temperatures below the upper limit temperature, i.e., below T<sub>max</sub>. Aligned below LED array 844 is a red LED array represented generally at 848. As before, each of the red indicators within array 848 is associated with a numerically assigned implant identifier as at numeric sequence 846. The LEDs at 848 will be illuminated at monitor temperatures above or closely approaching the upper limit temperature, for example, of 43°C. Above that temperature any so thermally influenced implant will cease to provide the assigned unique resonant center frequency.

Please replace the paragraph beginning at page 53, line 30 with the following corrected paragraph:

Looking additionally to Fig. 20, the thermal performance of the arrangement of Fig. 19 is schematically plotted. In this regard, the figure shows a time domain abscissa and a target tissue volume temperature ordinate. As the heater unit 862 is turned on, the temperature of the target tissue volume 806 will gradually increase as represented by plot component 872. During this interval, the blue LED indicators at array 834 will be illuminated as the target tissue temperature is below the lower temperature threshold level T<sub>min</sub> as represented at horizontal dashed line 874. When the temperature level 874 is approached, i.e., falls within the Curie transition range with a progressive ~~dimunition~~ diminution is the processed relative amplitude representing an assigned resonant center frequency, the LEDs of array 834 will turn

off, while those at array 838 will turn on with the noted green color. Typically a relative amplitude ~~dimunition~~ diminution by a factor greater than 2 (ratio of 0.5 or less) will trigger the LED performance. Resonant center frequencies of the lower threshold based implants at temperatures above their Curie temperatures will shift to a much higher resonant frequency which is not detected by the system. The heating control is now under the judgment of the operator 850 with LED arrays 838 and 844 being illuminated. During this thermotherapy period of time there may be excursions toward the upper limit target tissue temperature, T<sub>max</sub> as represented at plot component 876 and dashed horizontal line 878. As this temperature is approached, pertinent ones of the implants will exhibit a ~~dimunition~~ diminution of the processed relative amplitude representing their resonant center frequency and certain or all of the red LEDs within array 848 will illuminate. The operator then asserts control over the heater unit 862 to effect a lowering of the target tissue temperature as represented by plot component 880 and this sequence of events may continue for the interval of therapy as represented by subsequent plot components 882, 884 and 886. With the advantage of the predictable relative amplitude at center frequencies practitioners should be able to operate the system at hand such that the temperatures remain above T<sub>min</sub> at level 874 and below T<sub>max</sub> at level 878.

Please replace the paragraph beginning at page 56, line 22 with the following corrected paragraph:

It may be recalled that these ~~teatherless~~ tetherless implants will remain in place indefinitely and that the patient typically will undergo several therapeutic sessions. Accordingly, it is necessary that the implant information be recorded. Thus, the next line 962 is shown leading to therapy session procedures as labeled. Each of these procedures commences as represented at line 964 extending to block 966. At block 966, the practitioner reproduces the skin-carried markers if necessary. Next, as represented at line 968 and block 970 the patient is positioned upon a treatment fixture such as a table or chair such that the skin surface carried markers are clearly visible. Then, as represented at line 972 and block 974, guided by the skin-carried marker, the practitioner positions the heating assembly output component, for example, phased array antennae as close as practical to the target tissue volume. Additionally, as represented at line 976 and block 978, again guided by the skin-carried marker, the practitioner positions the excitation and receiver or sense antennae as close as practical to the target tissue volume. In this regard, the sense



antenna may be flexible and, in effect drapes over the body surface of the patient. Additionally, where necessary, as represented at line 980 and block 982 all of the recorded unique resonant center frequencies and associated sensor identification numbers are loaded into the interrogation assembly controller or data acquisition system. That interrogation controller then is turned on as represented at line 984 and block 986 and the procedure continues as represented at line 988 to the query at block 990. At this time, a determination is made as to whether all appropriate lower threshold and upper limit implants are resonating in response to monitoring or body level temperature, for example, with respect to Fig. 19 a determination is made as to whether the appropriate LEDs within array 834 are illuminated as well as the LEDs within array 844. If they are not, then as represented at line 992 and block 994 the practitioner again consults the implant map and carries out adjustments of the excite and sense antennae. The test at block 990 then is reiterated as represented at line 996 extending to line 988. Where the interrogation system is performing appropriately, then as represented at line 998 and block 1000 (Fig. 21E) the heating assembly is activated with the predetermined initial heating power level and, as represented at line 1002 and block 1004, a time-out of the maximum warm-up interval,  $t_{wu}$  commences. Next, as represented at line 1006 and block 1008 a check is next made as to whether all appropriate LEDs of arrays 838 and 844 (Fig. 19) are illuminated. In the event they are not, then as represented at line 1010 and block 1012 a determination is made as to whether the maximum warm-up time has timed out. In the event that it has not, the procedure continues as represented at line 1014 to the query posed at block 1016 again determining whether the LED arrays 838 and 844 are appropriately illuminated. In the event that they are appropriately illuminated, the procedure continues as represented at line 1018.

Please replace the paragraph beginning at page 58, line 2 with the following corrected paragraph:

Returning to the query posed at block 1016, where LED array 838 indicates that the target tissue volume temperature is above the lower threshold temperature,  $T_{min}$  and below the upper limit temperature as represented at LED array 846, then the program continues as shown at line 1018 to block 1034 representing the commencement of a session of a predetermined therapy duration. That therapy duration commences to be timed out. Where proper therapy temperatures are not present, the procedure reverts to node B as represented at line 1032. The program continues as represented at line 1036 leading to the query posed at block 1038 (Fig.

21G) where a determination is made as to whether any of the upper limit temperatures has been exceeded as indicated by an illumination of one or more LEDs within the LED array 848 (Fig. 19). In the event any such temperature elevation excursions have occurred, then the procedure reverts as represented at line 1040 to node A providing for the carrying out of adjustment of the heating assembly output component or components and heating power level. In the event of a negative determination with respect to the query posed at block 1038, then as represented at line 1042 and block 1044, a determination is made as to whether the therapy duration has timed out. In the event that it has not timed out, then the procedure reverts as represented at line 1046 to line 1036. Where the therapy duration has timed out, then as represented at line 1048 and block 1050 the heating assembly or unit and the interrogation assembly or controller are turned off and, as represented at line 1052 and block 1054, all therapy data are recorded and as represented at line 1056 and node 1058 the therapy session is ended. As noted above, in general, several therapy sessions will be involved in carrying out a complete treatment. The ~~unteathered~~ untethered nature and essentially permanent positioning of the implants beneficially facilitates the carrying out of several therapy sessions.

Please replace the paragraph beginning at page 61, line 21 with the following corrected paragraph:

Referring to Figs. 23A-23H a procedural block diagram is presented detailing the activities undertaken with the intermittent operation of the system as discussed in connection with Fig. 22. Looking to Fig. 23A, the procedure commences as represented at node 1120 and line 1122 extending to block 1124. As before, the practitioner elects the target therapy temperatures, for example, for hyperthermia and a consideration of HSP induction as well as susceptibility to adjunct therapies. Next, as represented at line 1126 and block 1128 the implants are selected for the target therapy temperatures. As before, the practitioner will consider a lower threshold based temperature sensing device as well as an upper limit based device. As represented at line 1130 and block 1132, the practitioner accesses target tissue imaging data concerning the location size and thermal response attributes of the target tissue volume. With that information, as represented at line 1134 and block 1136 the practitioner develops a preliminary implant placement pattern map with an identification of the sensors and/or auto-regulating heater implants. This map having been selected, as represented at line 1138 and block 1140 the practitioner selects and compiles the sensors such as the lower threshold temperature sensors and any

upper limit temperature sensor implants to be employed. Ex-vivo testing is carried out of the temperature sensing implants to determine that they are indeed developing the appropriate resonant center frequencies at monitoring temperatures below associated Curie point temperature. Next, as represented in Fig. 23B at line 1142 and block 1144 the interrogation assembly or data acquisition components are loaded with the unique resonant center frequencies involved and the associated sensor implant identifications. Next, a testing of the temperature sensor implants is carried out as represented at line 1146 and block 1148. This test determines whether the appropriate resonant center frequencies are detected at room temperature. That determination is represented at line 1150 and the query posed at block 1152. In effect, the test determines whether the appropriate LEDs of arrays of 834 and 844 are illuminated as described in connection with Fig. 19. In the event one or more of these LEDs is not illuminated, then as represented at line 1154 the procedure reverts to line 1138. Where all temperature sensor implants are performing at room temperature, then as represented at line 1156 and block 1158 an alternating current (ACF) field heating system, for example, an inductive system is elected and as represented at line 1160 and block 1162 an initial power level is selected for the heating system. Next, as represented at line 1164 and block 1166 the practitioner determines the maximum warm-up interval,  $t_{wu}$  for initially achieving the lower threshold minimum temperature,  $T_{min}$ . The practitioner then determines the therapy session duration at temperatures above the lower threshold and below the upper limit as represented at line 1168 and block 1170 (Fig. 23C). With this accomplished, as represented at line 1172 and block 1174 a general or local anesthetic agent is administered to the patient and, as set forth at line 1176 and block 1178, the target tissue volume is analyzed using such modalities as ultrasound, ~~stereotatic~~ stereotactic, or upright mammographic guidance or palpation. The temperature sensor implants are located as well as any auto-regulating heater implants at the target tissue volume in accordance with a preliminary placement pattern or map. Further, the skin surface of the patient's body is marked to identify the implant locations. As represented at line 1180 and block 1182 a determination is made as to whether the implants are in the proper location. If an implant is not properly located, then as represented at line 1184 the procedure reverts to line 1176. With the implants being properly located, then as represented at line 1186 and block 1188 any revisions to the implant pattern map are carried out and the program continues as represented at line 1190 and block 1192 where the skin carried marker location is recorded for future reference and all

resonant frequencies and associated sensor identification numbers further are recorded.

Please replace the paragraph beginning at page 63, line 6 with the following corrected paragraph:

As then labeled in conjunction with at line 1193, one or more therapy sessions are carried out. As noted above, inasmuch as the sensors are ~~unteathered~~ untethered and essentially permanently implanted, multiple therapy sessions can be carried out without a requirement for re-implanting such devices. As multiple therapy sessions are carried out, the skin carried marker may somewhat disappear. Accordingly, lines 1193 and 1194 extend to block 1195 (Fig. 23C) calling for the reproduction of the marker if necessary. Line 1196 and block 1198 provide for the positioning of the patient on a table or chair such that the marker is clearly visible and properly oriented. That marker, then as represented at line 1200 and block 1202, is utilized in positioning the heating assembly output component with respect to the target tissue volume. Additionally, as represented at line 1204 and block 1206 the interrogation assembly excitation and receiver or sense antennae are appropriately positioned. As noted above, the sense or receiver antenna is configured as being flexible and in effect drapes across the patient's body. From block 1206, as represented at line 1208 and block 1210 if not carried out beforehand, the practitioner loads all unique resonant center frequencies into the interrogation assembly controller. Then, as represented at line 1212 and block 1214 a test of the interrogation system is carried out by initially turning on the interrogation assembly controller and carrying out excite and sense cycles as represented at line 1216 and block 1218. A determination then is made as to whether all appropriate LEDs within arrays 834 and 844 as described in conjunction with Fig. 19 are illuminated. In the event that they are not so illuminated, then as represented at line 1220 and block 1222 the practitioner consults the implant placement map and adjusts the interrogation antennae appropriately. The procedure then returns to line 1216 as represented at line 1224. Where all appropriate LEDs have been illuminated, the procedure continues as represented at Fig. 23E and line 1226 and block 1228 providing for the actuation of the heating assembly with the initial heating ACF power level for a heating period. At the same time, as represented at line 1230 and block 1232 timing is commenced with respect to the warm-up time,  $t_{wu}$ . At the termination of the heating period, as represented at line 1234 and block 1236 the heating assembly is turned off and as

provided at line 1238 and block 1240 the interrogation controller is activated with the generation of the earlier-described excite and acquire signal activities. These activities are carried out for an interrogation interval and following that interval as represented at line 1242 and block 1244 a query is made as to whether the lower threshold LED array 838 and upper limit LED array as at 844 (Fig. 19) are illuminated to represent that the therapeutic temperature range has been reached. In the event of a negative determination to this query, then as represented at line 1246 and block 1248 a determination is made as to whether the warm-up time,  $t_{wu}$  has timed out. In the event that it has not timed out, then as represented at line 1250 and block 1252 the query posed at block 1244 is reiterated. Where these LED arrays are illuminated, the procedure continues as represented at line 1254. On the other hand, where all of the noted LEDs are not illuminated then the procedure continues as represented at line 1256 and node A. Note additionally, that in the event that the warm-up time,  $t_{wu}$  indeed has timed out in connection with the query at block 1248, then the procedure also extends as represented at line 1258 to node A.

Please replace the paragraph beginning at page 75, line 8 with the following corrected paragraph:

Figs. 27 and 28 illustrate an initial embodiment for a stent formed of non-magnetic material or material which can be heated from an extra body source, for example, by alternating current field heating and which initially incorporates an ~~unteathered~~ untethered temperature sensor which is fixed to it prior to the implantation. Looking to Figs. 27 and 28, the mesh-structured stent is represented generally at 1900 extending about a central axis 1902. Typically, such stents as at 1900 are formed of a non-magnetic inductively exercisable material, for example, austenitic stainless steel such as type 316, titanium, titanium alloys and nitinol. Non-magnetic materials are utilized inasmuch as they often will be located within the imaging field of highly magnetic devices such as MRI systems and the like. Stent structures are described in the following publications:

Please replace the paragraph beginning at page 75, line 22 with the following corrected paragraph:

\_\_\_\_\_The mesh-like generally cylindrically-shaped stent 1900 is seen to be implanted such that its outwardly disposed contact surface 1904 will have been urged into abutting and fixed intimate connection with the intima of a blood vessel 1906. Fixed to contact surface 1904 at the central region of stent 1900 is an ~~unteathered~~ untethered temperature responsive assembly according to the invention

which is represented generally at 1908. Component 1908 is configured with the rod-shape of device 670 described in connection with Figs. 14 and 14A-14C. The ferrite core as described at 672 of the component will be formulated to develop a Curie transition at an upper temperature limit as described above. That upper temperature limit is elected inasmuch as the instant embodiment includes only one passive device with a signature resonant center frequency. Sensor 1908 may be bonded with the stent 1900 and its securement may be further assured by the positioning of a biocompatible flexible sheath or band 1910 over the central portion of the stent 1900 and over the outwardly disposed surface 1912 of the sensor assembly 1908. Band 1910 may, for instance, be formed of a biocompatible, non-metallic material such as silicone elastomer, Dacron or Teflon. The arrangement is seen to slightly additionally distend blood vessel 1906 at region 1914. If desired, the sensor assembly 1908 may be mounted in intimate thermal exchange relationship with the stent 1900. Providing a biocompatible electrically insulated conformal coating such as the earlier-described Parylene as shown at 1916 in Fig. 28 is beneficial and may promote adhesion of the sensor 1908 to stent 1900.

Please replace the paragraph beginning at page 76, line 13 with the following corrected paragraph:

The combined stent and ~~unteathered~~ untethered sensor components discussed in conjunction with Figs. 27 and 28 also may be utilized to implement a thermally activatable drug release feature. Referring to Figs. 29 and 30, a stent represented generally at 1920 with a centrally disposed axis 1922 is shown having been implanted within a blood vessel 1924. Attached to the outer contact surface 1926 of stent 1920 is an ~~unteathered~~ untethered passive resonant circuit based sensor component 1928. Sensor component 1928 may, as before, be configured as described in connection with Figs. 14 and 14A-14C. Component 1928 may be fixed in thermal exchange relationship with the contact surface 1926 and further may be coated with an electrically insulated conformal biocompatible coating 1930 such as the earlier-described "Parylene" which functions to aid in the securement of the sensor to the stent 1920. This securement is further enhanced by a flexible band or sheath 1932 surmounting both the stent 1920 and the passive resonant sensor component 1928. Band 1932 may be structured in the manner of earlier-described band 1910. Note, however with the arrangement of Figs. 29 and 30 that the inward surface 1934 of stent 1920 is coated with a thermally activatable drug release coating as shown at 1936. The release coating will have a thickness which may fall

within the range of about 0.001 inch (0.025mm) to about 0.20 inch (5.0mm) and preferably will fall within a range of from about 0.005 inch (0.13mm) to about 0.10 inch (2.5mm). Such drugs may be provided, for example, as paclitaxel and the antibiotic Sirolimus as well as anti-thrombogenic agents such as heparin and the like. See the following publications in this regard:

Please replace the paragraph beginning at page 77, line 20 with the following corrected paragraph:

The ~~unteathered~~ untethered passive resonant circuit based sensors preferably are positioned on the outer contact surface of the stent structure, inasmuch as such location provides a factor of safety with respect to the adhesion of the individual components to that contact surface. Should the coupling be damaged, the sensor components are retained by the stent structure itself outside of luminal blood flow. In addition, the detectable signal amplitude issuing from the passive resonant circuit is greater if the sensor is placed on the outside of a metallic stent.

Please replace the paragraph beginning at page 77, line 27 with the following corrected paragraph:

Two of these resonant circuit based passive sensors may be employed to provide the earlier-described lower threshold temperature sensing and upper limit temperature sensing. Additionally, multiple sensors may be employed to provide a redundancy. Figs. 31 and 32 illustrate a stent structure with lower threshold and upper limit temperature value sensors in conjunction with a nonmagnetic stent represented generally at 1940. Formed, as before, of a nonmagnetic material, stent 1940 is seen disposed about a central axis 1942 and has a generally mesh-like structuring with an outwardly disposed contact surface 1944 of generally cylindrical configuration. ~~Unteathered~~ Untethered passive resonant circuit based lower threshold and upper limit temperature level sensors are shown respectively at 1946 and 1948 coupled to contact surface 1944 at diametrically opposite locations. As before, each of these sensors may be configured in the manner described in connection with Figs. 14 and 14A-14C. The assembly additionally may be coated with an electrically insulative biocompatible material represented at 1950 in Fig. 32. That material, which may be the earlier described "Parylene" functions to enhance the bond between the sensors and the outer contact surface 1944. Sensors 1946 and 1948 further are secured to the contact surface 1944 by a flexible band or sheath 1952. Band 1952 is structured in the manner of the earlier-described band 1910. As

before, the instant figures reveal that the blood vessel 1954 within which stent 1940 is positioned is diametrically enlarged at regions 1956 and 1958 to accommodate for the thickness of sensors 1946 and 1948 as well as band 1952.

Please replace the paragraph beginning at page 78, line 21 with the following corrected paragraph:

Referring to Figs. 33 and 34, an asymmetrical retrofitting design is illustrated. In the figure, a nonmagnetic metal mesh stent is represented in general at 1962 disposed about a central axis 1964 which has been previously implanted within a blood vessel 1966. Note in this regard that the outwardly disposed surface 1968 of the stent 1962 is in contact with the intima of the vessel 1966. The ~~unteathered~~ untethered passive resonant circuit based temperature sensor carrying insert or support member is seen at 1970 disposed about central axis 1964. Insert 1970 is of generally cylindrical configuration with an interior surface 1972 and exterior surface 1974 to which an ~~unteathered~~ untethered passive resonant circuit based temperature sensor 1976 is bonded. That bond may establish a temperature exchange relationship between the insert and the stent. In general, the insert 1970 may be formed with essentially the same mesh structuring and material as present in the previously implanted stent 1962. Such mesh structuring is not shown in the figures in the interest of illustrational clarity. Fig. 34 shows that the insert and associated sensor is coated with a biocompatible coating 1978 which may be provided as the earlier-described "Parylene" material. Additionally, the structural integrity of the attachment of the sensor 1976 is enhanced by a flexible band 1980. Sensor carrying insert or support member 1970 is inserted within the preexisting stent 1962 using balloon angioplasty procedures. In order to accommodate for the asymmetrical positioning of only a single sensor 1976, the insert member 1970 is structured so that it is preferentially expandable in the region 1982 immediately beneath the sensor 1976. Accordingly, upon balloon expansion during the placement of insert 1970, the region 1982 will expand from an initial insertion diameter diametrically outwardly against the interior surface 1984 of the preexisting stent 1962 to create the crimping expansion of the contacting surface of that stent 1962 as represented at region 1982. Preferential expansion of the insert 1970 can be provided by structuring the stent to be thinner at that region and/or the mesh structure opening size may be asymmetrically varying.



Please replace the paragraph beginning at page 80, line 21 with the following corrected paragraph:

The instrumentation described in connection with Figs. 19 and 25 in general may be employed for carrying out the heating of nonmagnetic stents as described above. Where inductive heating components are utilized then the intermittent form of operation of the system is called for. However, U. S. Patent No. 6,451,044 (*supra*) describes an ultrasound heating of a stent formed of an ultrasound ~~absorptive~~ absorptive material. Such a stent therefore could be heated while continuous temperature monitoring is carried out. Looking to Fig. 37, the instrumentation and support equipment discussed in connection with Fig. 25 are illustrated for exemplary purposes in connection with a patient 2030. Patient support components, heating components and interrogation components which are repeated from Fig. 25 are shown with the same earlier presented numerical identification but in primed fashion. Stent 1940 (Fig. 31) reappears adjacent the heart region 2032 of patient 2030. Heating component 1557' is located in adjacency with the stent 1940. Excitation coil 1530' is located for exciting the temperature sensors of stent 1940, while the sense antenna 1542' is positioned about the region of the stent 1940 location. The instantaneous heating power generated within the stent 1940 will generally fall with a range of from 0.20 calories/second to about 20 calories/second and preferably will be within a range of between about 0.5 calories/second and about 10 calories/second. The nominal hyperthermia therapy temperature for stents such as at 1940 will fall within a range of from about 39°C to about 70°C and preferably within a range from about 41°C to about 50°C.

Please replace the paragraph beginning at page 86, line 11 with the following corrected paragraph:

The passive resonant circuit based sensor implant of the invention also may be implemented utilizing an inductive component exhibiting substantially uniform relative permeability over a temperature range of interest, for example, between 40°C and 45°C in combination with a capacitor component which exhibits capacitance values as a function of temperature. The involved passive resonant circuit will physically appear essentially identical to that described in connection with Figs. 7 and 14 and 14A-C. Looking to Fig. 40, an inductor is represented generally at 2340 as comprising a ferrite core 2342 about which are provided the turns 2344 of an inductive winding. These ~~turns~~ turns 2344 are coupled in series, as represented at leads 2346 and 2348, to the oppositely disposed plates of a capacitor 2350, the

capacitance values of which vary with temperature. In this regard, referring to Fig. 41 the capacitance exhibited by capacitor 2350 may be represented by the curve 2354 as it extends between capacitance values C1 and C2 within a range of temperatures, for example, between 40°C and 45°C. The value of capacitance is given by the expression:

$$C = (\text{const.}) (\epsilon A)/d$$

where: C is capacitance;

$\epsilon$  is the dielectric constant;

A is plate area; and

d is the distance between the capacitor plates.